# Minutes of the meeting
# of representatives of the Medicines Patent Pool and the EECA community

**June 9, 2025**

**Organization:** **Medicines Patent Pool (MPP)**

**Name, title:** **Lobna Gaayeb, Head of Scientific and Medical Affairs, MPP**

**Name, title:** **Mila Maistat, Senior Manager, Policy, Strategy, and Market Access, MPP**

**Start of the meeting. Introduction of participants.**

**Presentation of the Medicines Patent Pool (MPP).**

Good afternoon. We would like to start by thanking the organisers for setting up this meeting and inviting us to discuss. The MPP work towards increasing access to life-saving medicines relies on a prioritisation framework whereby we analyze data on new drugs and health technologies in key health areas, and then assess if and how the MPP could contribute to expand access to those candidates in LMICs. In particular, we look at how safe and effective a drug could potentially be, whether it is included in the World Health Organization (WHO) guidelines, and, in the case of hepatitis, whether the drug is included in the EASL and AASLD guidelines. We also look at the intellectual property landscape, and other criteria such as service delivery enablers, manufacturing aspects, market analysis and regulatory aspects. If the result of this assessment shows that the MPP may have a role to increase access, then we add them the candidate to the prioritisation list.

The prioritisation framework, prioritisation list and annual prioritisation reports are publicly available here.

Essentially, the list includes two categories: priority and watchlist medicines. The drugs in the watchlist are the ones that we are currently only monitoring. These include drugs for which expanded access could provide significant health benefits but for which supporting data are lacking and/or key challenges need to be addressed for expanded access through MPP licensing to lead to public health impact.

Only those drugs clearing the prioritisation criteria mentioned above are formally prioritised. As such, we consider as priorities, the drugs for which voluntary licensing through MPP would lead to expanded access, significant health benefits, and substantial public health impact compared to standards of care. For these, we seek to enter into discussions with the originators (pharmaceutical companies, universities or other patent holders).

Bulevirtide was on the list of drugs in watchlist until 2025. It was removed this year because the primary patents will expire in January 2029 and no secondary patents were identified in LMICs. If we consider the time to get a licence, and to develop the product can get regulatory approval, it is likely that patents will be expiring or have expired, meaning that manufacturers would no longer need a licence.

## Bulevirtide compound patent coverage

| Granted patent* with expected expiry 25.01.2029 | Granted patent with term extended to 25.01.2034 |
|---|---|
| Australia, Brazil, China, India, Japan, South Africa, Turkey, USA | France, Germany, Italy, Netherlands, Russia, Spain, Sweden, United Kingdom |

**Possible re-registration** of a patent already granted in another country**

Belize (UK), Bermuda (UK), Cayman Islands (UK), Fiji (UK), Gibraltar (UK), Hong Kong (China), Kiribati (UK), Macao SAR (China), Nauru (AU, US, UK), Saint Lucia (UK), Saint Vincent and the Grenadines (UK), Seychelles (UK), Sierra Leone (UK), Turks & Caicos (UK)

**Patent not in force*****

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Switzerland

**Compound patent not filed**

Afghanistan, Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, Chad, Channel Islands, Chile, Colombia, Comoros, Congo, Congo, Dem. Rep., Costa Rica, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Faeroe Islands, Gabon, Gambia, Georgia, Ghana, Greenland, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Indonesia, Iran, Iraq, Israel, Jamaica, Jordan, Kazakhstan, Kenya, Korea, Dem. Rep., Korea, Rep., Kosovo, Kuwait, Kyrgyzstan, Laos, Lebanon, Lesotho, Liberia, Libya, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, New Zealand, Nicaragua, Niger, Nigeria, Oman, Pakistan, Palau, Palestine, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Qatar, Rwanda, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Singapore, Somalia, South Sudan, Sri Lanka, St. Kitts and Nevis, Sudan, Suriname, Syria, Taiwan, China, Tajikistan, Tanzania, Thailand, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Yemen, Zambia, Zimbabwe

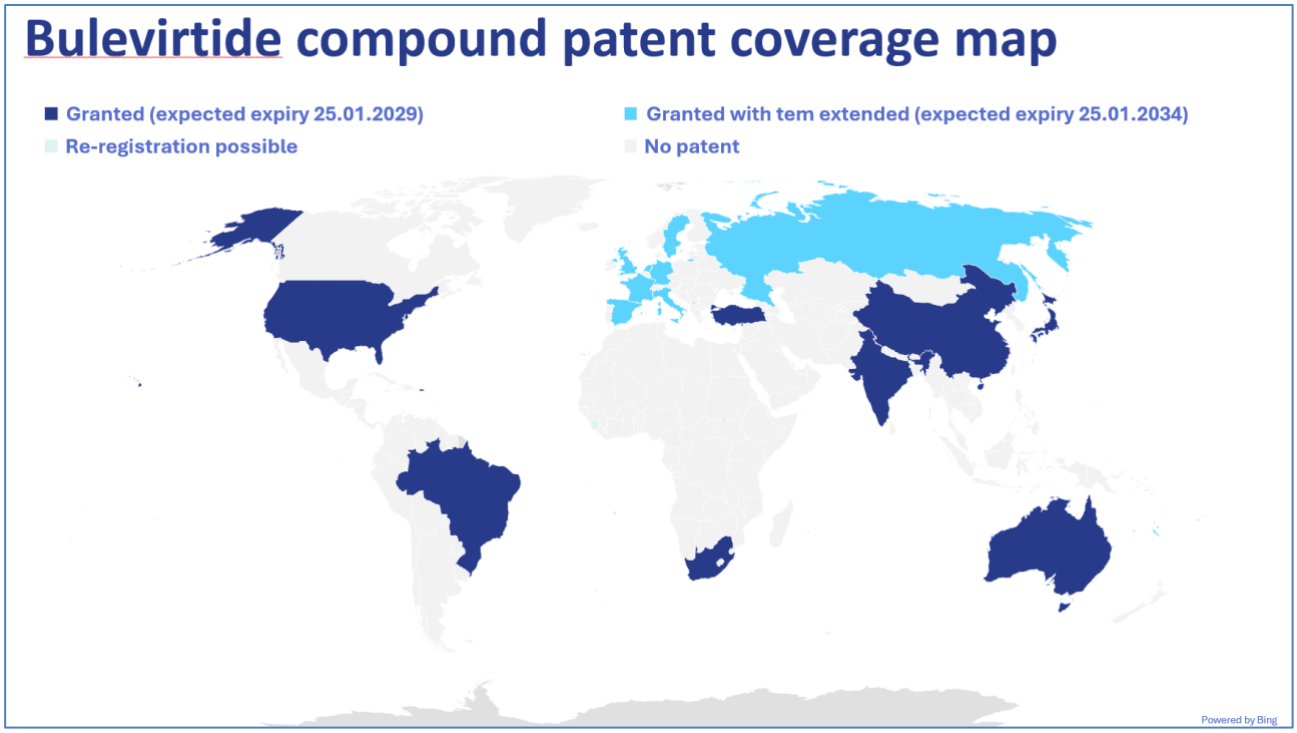
* Following territories apply granted patents from corresponding countries: American Samoa (US), French Polynesia (France), Curacao (Netherlands), Guam (US), Isle of Man (UK), New Caledonia (France), Northern Mariana Islands (US), Puerto Rico (US), Sint Maarten (Netherlands), Saint Martin (France), Virgin Islands (US)

** Re-registration is the process of obtaining patent protection in a new country or jurisdiction after a patent has already been granted in another, which can be applied for within a certain time from grant in the original country

*** Not in force due to regional patent (e.g. European Patent Office, or Eurasian Patent Office) not having been validated in the country, or patent lapse due to non-payment of maintenance fees

This slide shows the countries where bulevirtide is patented and those where it is not. As you can see, the drug is patented in Australia, Brazil, China, India, South Africa, Turkey, and the United States. The patent expires in these countries in January 2029. In France, Germany, Italy, the Netherlands, Spain, Russia, Sweden, and the United Kingdom, the patent expires in January 2034.

## Bulevirtide compound patent coverage map




This map shows in dark blue the countries where the patents expire in 2029 (patent family represented by international patent publication WO2009092611). These are mainly high-income and some upper-middle income countries. Countries where the drug is not patented are marked in gray. And, as you can see, there is no patent in EECA countries except Russia. A patent term extension was granted in Russia extending the patent term of **RU 2 492 182** to **26.01.2034.** This extension is associated

to **Mircludex B®** approved in Russia on **28.11.2024** for "treatment of chronic hepatitis B with delta agent (chronic hepatitis D) in adult patients" to the company Gepatera. This company has licensed the rights to the Russian patent in the name of the University of Heidelberg entered into the patent register in May 2025. To our knowledge, there are no relevant secondary patents.


On this slide, you can see the countries divided by region with no patent for bulevirtide.

In most low and middle-income countries (LMICs), to the best of our knowledge, a patent for bulevirtide was not filed.

**Continued presentation. How does the Medicines Patent Pool prioritize drugs?**

We have a prioritization system that is recognized by the Access to Medicines Index as an excellent mechanism for prioritizing medicines.


When it comes to prioritization, you can see three squares at the top that play a key role: the burden and prevalence of the disease, existing treatment options, and how severe the disease is and how high the risk of an epidemic is. Another important factor is the clinical significance of the drug (safety and efficacy), the regimen and dosage, and, of course, intellectual property.

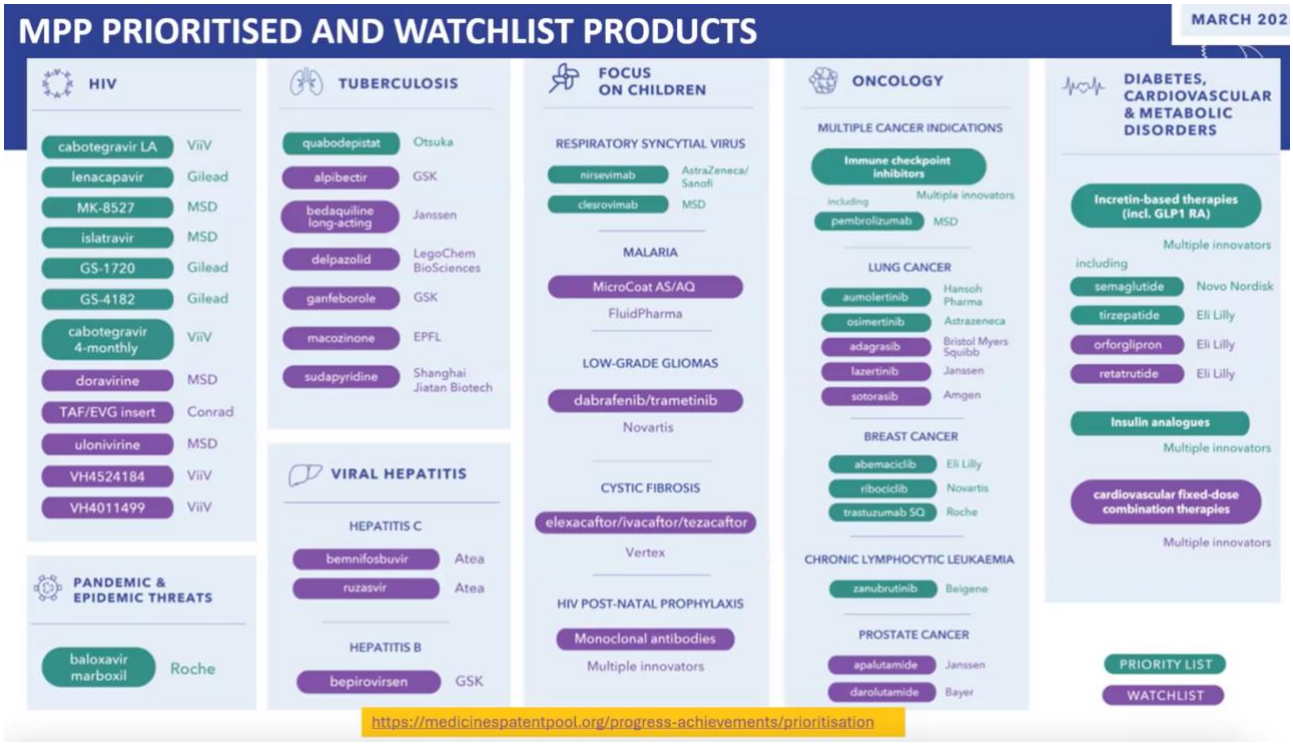
When it comes to intellectual property, the number of years remaining before the patent expires is taken into account, because at a certain point, given the length of all the procedures (not only the paerperwork, but mainly the development of the technology and regulatory aspects at the generic manufacturer level), it no longer makes sense to start the licensing process. Geographic coverage, the presence or absence of secondary patents, and the number of patent owners are also taken into account.

Furthermore, there are factors that facilitate access to the healthcare system and service delivery, such as diagnostics, concomitant medications that need to be taken, and other healthcare requirements.

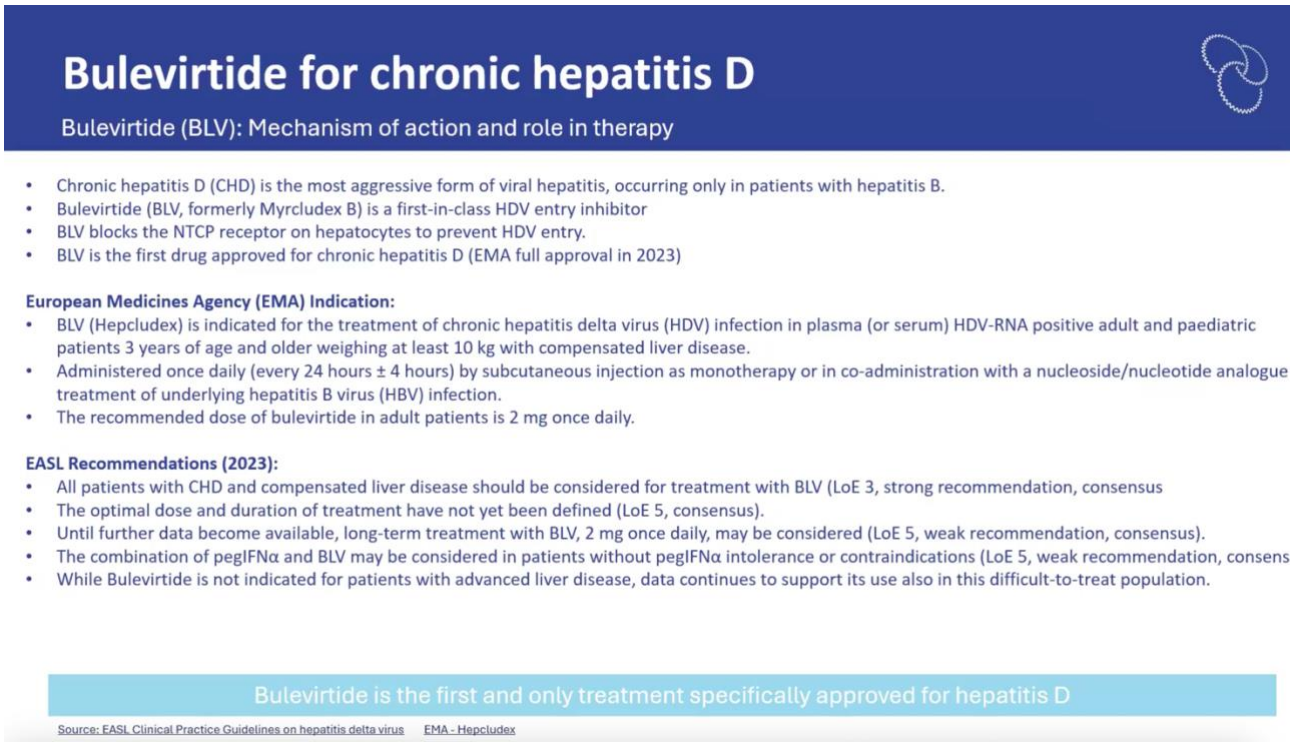
The next factor is production, i.e., how easy it is to manufacture the drug, what requirements are set for delivery and storage.

When it comes to the regulatory aspect, we look at how the registration process will proceed, how complex and expensive it will be, whether clinical trials will be required, etc.

And the last aspect is the market, where we discuss how much savings can be achieved, the current cost of the originator drug and comparison with the standard of care cost, the potential buyers, the potential for generic production (commercial interest), etc. All these components will be part of the market analysis.




This slide shows an updated list of priority drugs and the progress that we are tracking. They are marked in two colors: green and purple. Those marked in green are our priorities, while those marked in purple are those we are monitoring and trying to understand if and how they may become prioritized in the future. The full report can be found on the Medicines Patent Pool website.

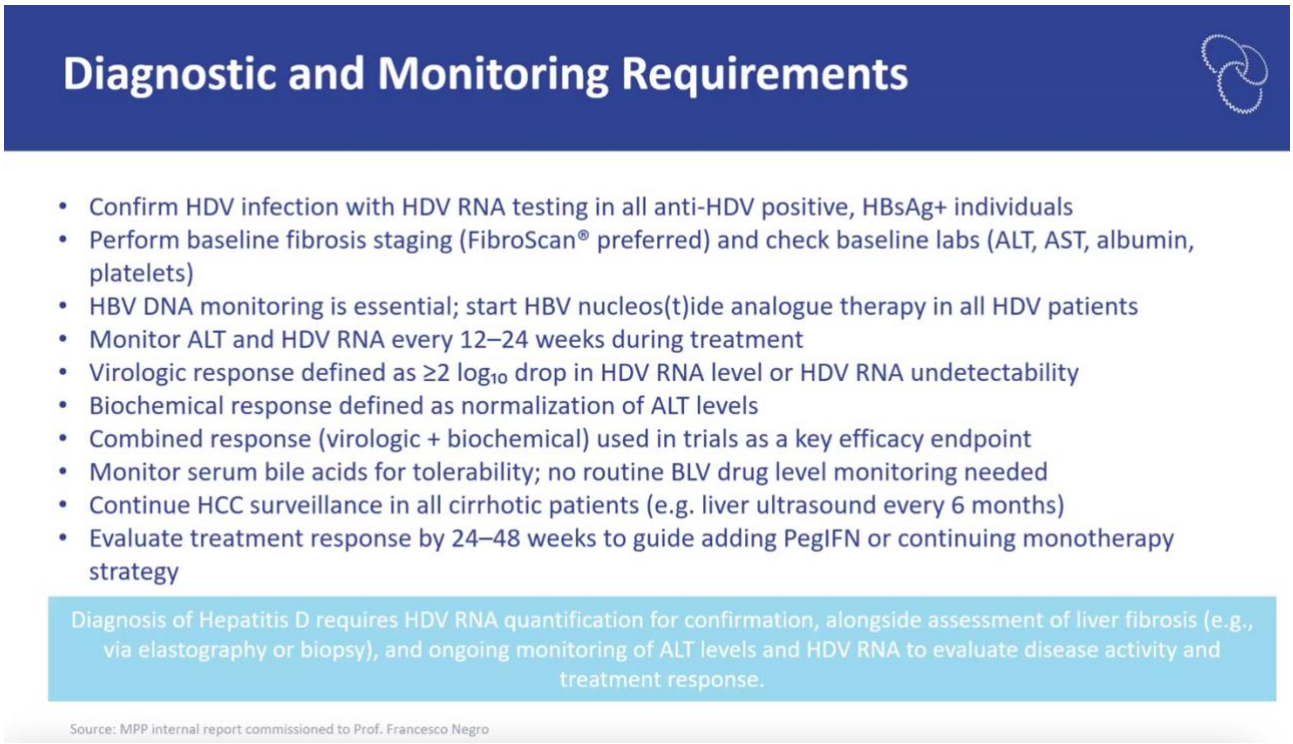



On this slide, you can see detailed clinical information about bulevirtide.

**Question:** The main clinical question that interests the patient community is how long treatment with bulevirtide should last.

**Answer:** In 2023, the drug was approved by the European Medicines Agency (EMA). Bulevirtide can be used in the treatment of chronic hepatitis delta both as monotherapy or in co-administration with a nucleoside/nucleotide analogue treatment of underlying hepatitis B virus (HBV) infection. The optimal duration of the therapy is not defined. The advice is to continue long-term as long as there is clinical benefit.

**Continued presentation.**




As for diagnostics, I would like to note the importance of monitoring the ALT (alanine aminotransferase) parameter throughout the entire treatment period, at intervals of 12–24 weeks. It would also be equally important to monitor and interpret correctly the development of fibrosis using FibroScan.

From the point of view of monitoring the effectiveness of treatment, it is important to assess the level of virological response after some time.


To sum up everything that can be said about the practical application of bulevirtide, it is important to note that the drug is safe and well tolerated. It is mostly observed that the long-term use of the drug leads to significant improvements in terms of virological and biochemical markers. At present, there are no clear recommendations on when and whether to discontinue bulevirtide therapy. Most likely, for most patients, the drug is indicated for life. Its effectiveness has also been confirmed in patients with cirrhosis, and the drug helps to achieve clinical stability in such patients. Real-world results indicate a "low" incidence of hepatic complications with bulevirtide therapy but this has to be confirmed from further studies.

**Question:** Do you have any information about how complex the production process for bulevirtide is?

**Answer:** We cannot answer that question at this time, as that information is not publicly available. As we have already said, we first evaluate a drug based on the following parameters: clinical significance, disease burden, and intellectual property landscape. And since the drug did not meet the criteria for the first three parameters, we did not delve into the details of its production.

**Question:** I know from patients from Ukraine who are receiving treatment in Germany that after 2.5 years, the hepatitis delta virus is no longer detectable and a sustained virological response is observed. Patients are then offered to discontinue the drug and see how the virus behaves in the future. Is it correct to understand that medical professionals do not have sufficient data on the duration of bulevirtide use? What data do you have on the duration of treatment?

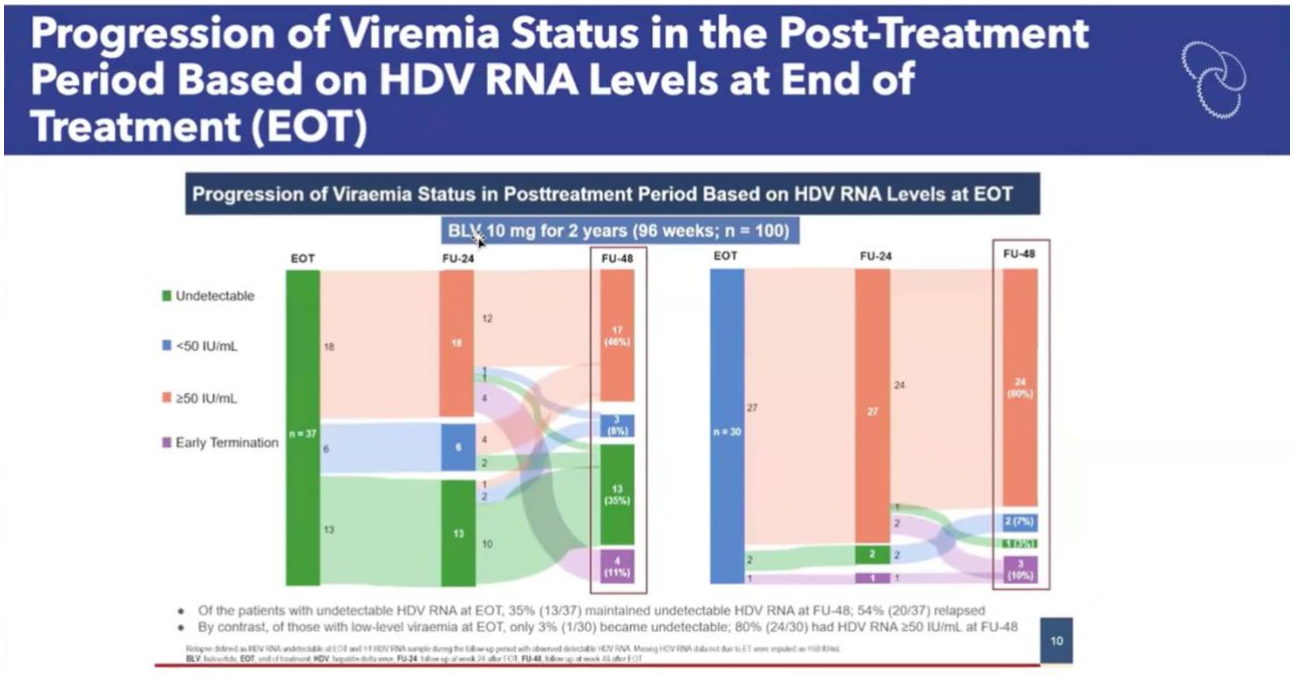
**Answer:** I am glad that patients from Ukraine are receiving treatment and have a sustained virological response. And I hope that their viral load will remain suppressed. As far as I know, there is no official guidelines that would recommend discontinuing the drug after achieving a virological response. Perhaps in this particular case, healthcare workers decided to discontinue treatment based on other factors.

**Comment from a representative of the patient community:** It may also be due to the price of the drug.

**Comment from a representative of the patient community:** We see that the guidelines of some countries say that the drug is prescribed to patients for only one year, and then a medical commission assesses the patient's condition and decides whether to extend treatment.

**Question:** As far as I know, in the case of these particular patients, the issue is not about the price. The patient was offered to pause treatment based on positive test results. As I understand it, medical professionals want to see for themselves what will happen next with the patient, since they do not have the data themselves. It is important to clarify that the patient was taking the drug without pegylated interferon.

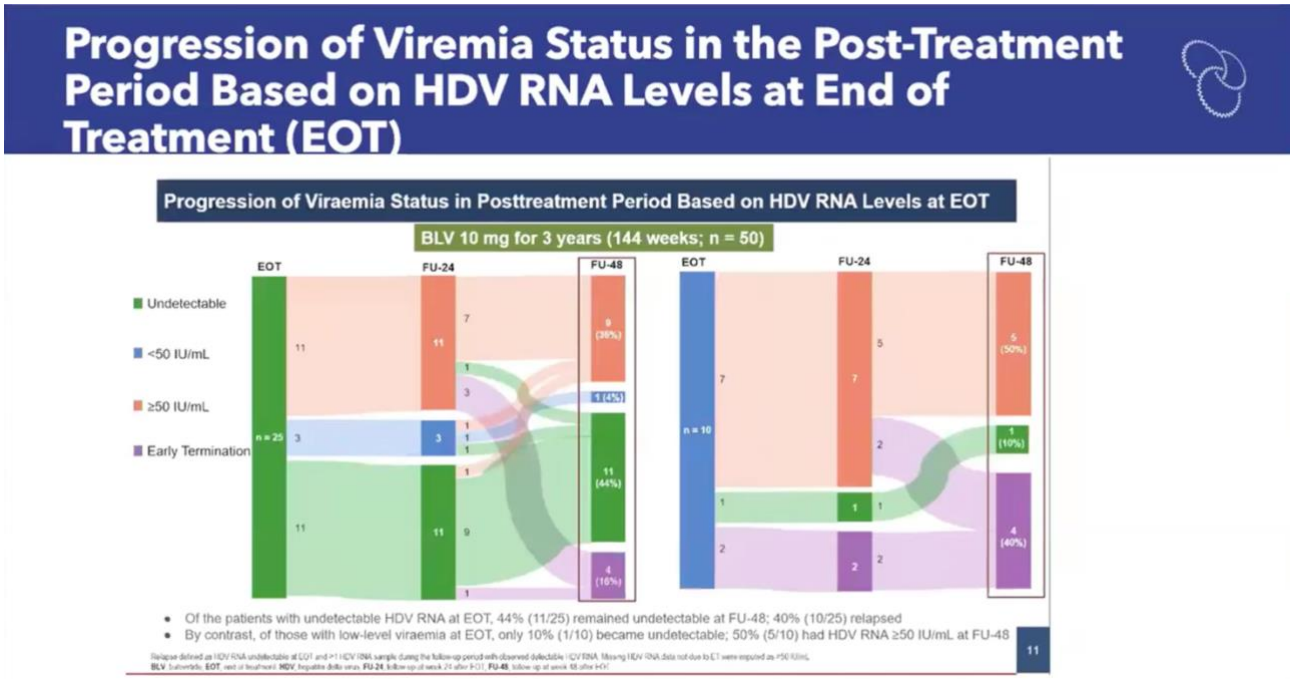
**Answer:** To try to answer these questions, we would like to use slides that were presented at EASL meeting.




Source: https://www.natap.org/2025/EASL/EASL_30.htm

This slide shows the progression of viremia in persons receiving 2 years (96 weeks) of bulevirtide 10 mg once daily. If you look at the left graph, you will see 37 patients (37 % of the intitial group) who had an undetectable viral load at the end of the treatment period. Twenty-four weeks after discontinuation of treatment, a repeat analysis was performed, which showed that only 13 patients remained undetectable, 6 patients had less than 50 copies, and 18 patients had more than 50 copies. At week 48, approximately 35% of the 30% (13% of the initial cohort) had undetectable viral loads.

The graph on the right shows that in 30 patients (30% of the initial cohort) for whom viral load was detectable but lower than 50IU/mL after 2 years of treatment, 80% rebounded to higher than 50 after 48 weeks of treatment discontinuation. In other words, the data shows that to maintain sustained undetectable HDV RNA, patients must be HDV RNA undetectable at end of treatment, after 2 years of treatment. Unfortunately, less than 50% of patients do not reach undetectable HDV RNA at the end of 2 years of treatment.

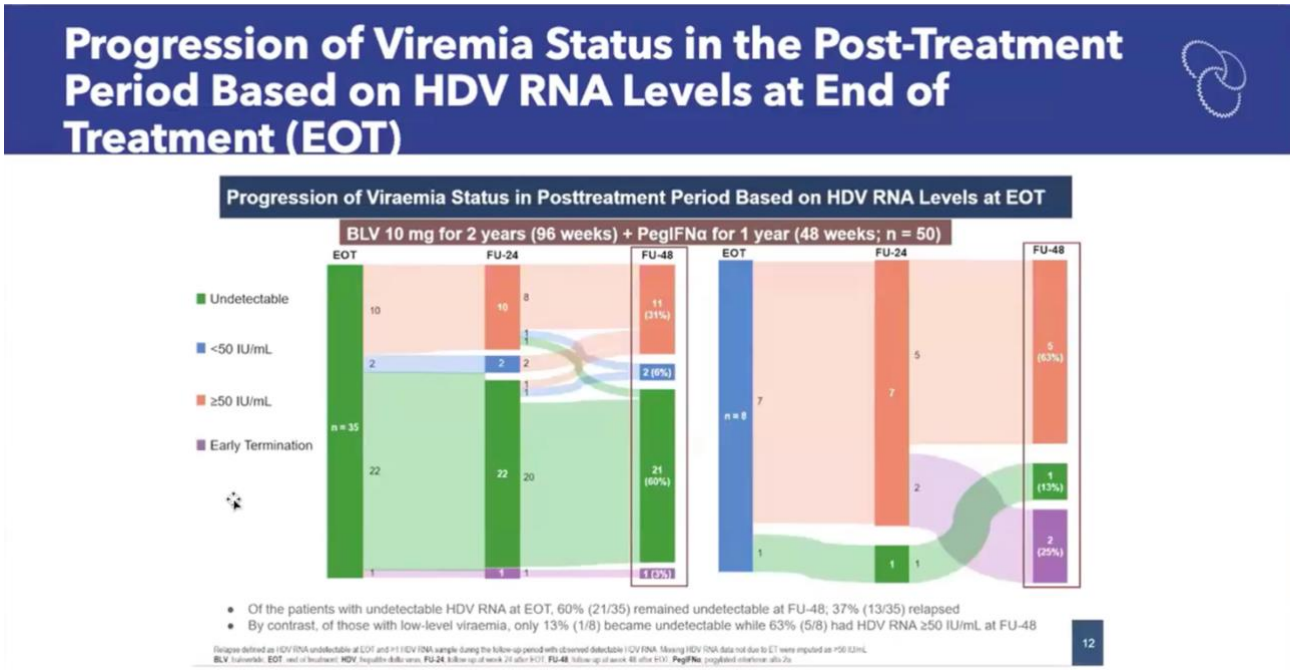



Source: https://www.natap.org/2025/EASL/EASL_30.htm

On this slide, you can see a similar study involving 50 patients for 3 years treatment with daily oral bulevirtide 10mg. Only 50% of patients (25 patients) had an undetectable viral load after 3 years of treatment. We can see that by week 48 after treatment discontinuation, 44% of those remained undetectable (around 25% of the initial cohort).

On the right graph, you see 10 people who completed treatment with a detectable viral load of less than 50 copies. Of these, by week 48 after completion of treatment, almost all had a detectable viral load.

In other words, the data shows that to maintain sustained undetectable HDV RNA, patients must be HDV RNA undetectable at end of treatment, after 3 years of treatment. Unfortunately, only 50% of patients reach undetectable HDV RNA at the end of 3 years of treatment.




Source: https://www.natap.org/2025/EASL/EASL_30.htm

This slide shows the results of a study in which patients took bulevirtide 10mg daily for 2 years and pegylated interferon for one year. A total of 50 patients participated in the study, 35 of whom achieved an undetectable viral load after two years of treatment (left graph). Forty-eight weeks after the end of treatment, approximately 60% of patients (around 42% of initial cohort) remained undetectable.

We hope this helps clarify what we know regarding the duration of treatment with bulevirtide.

**Question:** Is this patent, which is currently valid in Russia, a secondary patent? Or are there several patents in force there? And do you know who holds the patent in Russia?

**Answer:** There is a compound patent for bulevirtide in Russia (please see the patent coverage map above).

In fact, the 20 years expiry date of the basic compound patent is **26.01.2029**. In addition, a patent term extension was granted in Russia extending the patent term of **RU 2 492 182** to **26.01.2034.** This extension is associated to **Mircludex B®** approved in Russia on **28.11.2024** for "treatment of chronic hepatitis B with delta agent (chronic hepatitis D) in adult patients" to the company Gepatera. This company has licensed the rights to the Russian patent in the name of the University of Heidelberg entered into the patent register in May 2025. To our knowledge, there are no relevant secondary patents.

It would be good to hear from you whether the drug is being manufactured and sold in Russia and whether patients are receiving it.

**Comment from a representative of the patient community:** Yes, the drug is indeed manufactured in Russia by a Russian company, and as of 2023, 1,000 people received it. However, this company completed phase 3 clinical trials only five months ago, but the patent expires in three years. We ourselves do not understand why, for example, the drug is not registered in Kyrgyzstan, Belarus,

Kazakhstan, or Armenia. It is also surprising that the patent is expiring, but we do not have sufficient data on the drug.

**Question:** Have you been in contact with any companies that could manufacture the drug? As a community, we are interested in seeing generic companies enter the market after the patent expires. I would also like to add that I did not see any other drugs for the treatment of hepatitis delta on your list of drugs "under observation," although we know that such drugs exist and are already showing good results in studies.

**Answer:** We have not negotiated the possibility of manufacturing of generic bulevertide with generic companies because we do not have a license for the medicine. We only open the expression of interest (EoI) process for generic companies when a licence has been signed between the originator company and MPP.

**Question:** As for other breakthrough drugs that we would like to learn more about, there are three: brelovitug (human monoclonal antibody IgG1, Bluejay), lonafarnib (farnesyl transferase inhibitor, Eiger BioPharmaceuticals), and tobevibart + elebsiran (antibody + siRNA to block HBsAg and viral entry, Vir Biotechnology).

**Answer:** In general, all these molecules are at approximately the same stage of development. The most advanced drug is Bulevirtide and possibly lonafarnib. At the moment, all drugs are in the second stage of clinical trials, and there is not enough data yet to appropriately assess them. But we are closely monitoring these developments.

I would also like to add that the WHO recognizes that bulevirtide may be effective in treating hepatitis delta, but at the moment there are no guidelines for this drug. And as far as we know, the drug has been approved by the EMA, but not by the FDA (US Food and Drug Administration).

**Question:** What does it mean in practice for patients that the drug is not included in the WHO guidelines and is not approved by the FDA, but is included in the EASL guidelines and approved by the EMA? Will the drug be available in the EECA region and will it be accessible to patients?

**Answer:** We believe that, in the first place, more data is needed. As far as we know, in order for the WHO to recommend a drug, they need to gather more compelling data. There is data that the drug is effective, but there is no consistent data on the duration and discontinuation of treatment. There is also the question of the injectable method of administration, i.e. how difficult it is for patients to store, reconstitute and self-administer, as well as the need for monitoring. The WHO is also looking at new drugs and awaiting data on them.

**Comment from a representative of the patient community:** Patients from Ukraine who receive treatment with bulevirtide in Germany are given a prescription, and they purchase the drugs at a pharmacy for 2 or 3 months and administer the injections themselves. And patients do not have any problems.

**Comment from a representative of the patient community:**

Also, at the last meeting with Gilead, they shared with us information that the rights to the drug in the EECA region belong to the Russian company Hepatera, which is a huge barrier for patients in

Ukraine. We are already communicating with Gilead and Hepatera on this issue, and as soon as we have information, we will share it immediately.

**End of meeting.**